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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/303,315	04/30/1999	EUGENE S. PEARLMAN	108604/002	8170

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Rashida A. Karmali, PhD
99 Wall Street
13th floor
New York, NY 10005

EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/303,315

Applicant(s)

PEARLMAN, EUGENE S.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-17, 19-21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 13-17, 19, 20 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 21, 23, 24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' response, filed 27 January 2005, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-11, 13-17, 19-21, and 23-27 are currently pending. Claims 5-11, 13-17, 19, 20 and 25 are withdrawn from consideration. Claims 12, 18, and 22 were cancelled.

Claim Objections

Claim 4 recites "code of claim 3". This is repetitive, as "the method of claim 3" was previously recited. Correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-4, 21, 23, 24, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the method steps do not reflect the intention of the preamble as currently written. Please see specific rejections below.

The preamble of Claim 1 recites “a method for optimizing a clinical diagnosis”. However, there is no method step of “optimizing” recited. Step (g) is a step of rendering a complete diagnosis, however it is not a step of “optimizing”. Clarification is requested.

The preamble of Claim 1 recites “using a disease specific algorithm”. However, there is no step of actually using an algorithm in the method steps. Clarification is requested.

The preamble of Claim 1 recites “a system to self-monitor”. However, there is no step of “self-monitoring” in the method steps of the recited claim. In addition, it is unclear what is to “self-monitor”, i.e. the system, the patient, the tests themselves, etc. Clarification is requested.

The preamble of Claim 1 recites “eliminating unnecessary tests”. There is no step of eliminating unnecessary tests in the steps of the method. Step (g) recites “avoiding unnecessary tests”, however this is not a limitation of the method, as it is merely an intended result. Clarification is requested.

Claim 1 recites, at step (e), “carrying out only the relevant tests defined in (d) to obtain at least one clinical value” and then at step (f) recites “sequentially running the relevant tests for each of the sub-groups of the suspected disease”. Step (f) is unclear as the relevant tests have already been carried out in step (e). Are the tests of step (f) different from the tests of step (e)? Are the same tests performed twice? Clarification is requested.

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Claim 1, step (f) recites “computing the next set”. There is insufficient antecedent basis for “the next set” in the claim. Clarification is requested.

Claim 1, step (f) recites “of said clinical test values”. It is unclear which clinical tests the values come from: those from step (e) or step (f). Clarification is requested.

Claim 1, step (g) is unclear in that steps (e) and (f) are repeated. Those steps are unclear, as stated above. Clarification is requested.

Claim 2 recites “performing a different clinical test”. It is unclear to what test this step is referring: is the clinical test intended to be “different” from that of step (e) or the clinical test of step (f) or some other test? Clarification is requested.

Claim 2 recites “to rule out a different diagnosis”. This is unclear as it is an intended result. The method step intended by this phrase is unclear. Clarification is requested.

Claim 4 recites “to implement any modifications “. It is unclear whether or not this is intended to be an active positive step of “optimally modifying the diagnostic algorithm” or not. Clarification is requested.

Claim 24 recites “wherein m equals at least one”. This fails to further limit claim 21, which recites “m is an integer greater than one”. The “at least one” of claim 24 encompasses “one” whereas the “greater than one” of claim 21 specifically excludes “one”. As the range intended for m in claim 24 is unclear, claim 24 is indefinite. Clarification is requested.

Claim 26 recites “the Hepatitis Algorithm”. There is insufficient antecedent basis in the claim for “the Hepatitis Algorithm”. Clarification is requested.

Claim 27 recites “the hepatitis B algorithm”. There is insufficient antecedent basis for “the hepatitis B algorithm” in the claim.

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Claim 27 recites “the clinical tests”. It is unclear which clinical tests are intended, as several sets of tests are recited in parent claim 1. Clarification is requested.

Claim 27, step (b) recites “defining each of the clinical tests listed in (a)”. It is unclear which tests are being defined. Further, it is confusing because in claim 1, tests are already defined. Clarification is requested.

Claim 27, step (d) recites “computing the next set”. There is insufficient antecedent basis for “the next set” in the claim. Clarification is requested.

Claim 27, step (f) recites “computing a next portion of the diagnostic algorithm”. This is unclear because a first portion was never computed. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 21, 23, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,099,469 (Armstrong et al.).

Armstrong et al. teach a system for optimizing clinical diagnosis of a disease using a diagnostic algorithm. The abstract outlines that a “reflex algorithm for assessing cardiac patients, which does not require human decision-making in selecting assays to be performed”. Further, “the algorithm can be implemented on a computer” (abstract). The system contains a memory, as required by step (a) of claim 21 (see Figure 2). The system contains a means of selecting tests necessary to diagnose a suspected disease from tests ordered by a physician (column 5, lines 13-19). In addition, the system can read out tests from memory, wherein test are equal to more than one test (or at least one test, as in claims 23 and 24) (column 12, lines 46-67 to column 13, lines 1-11). Finally the system outputs a diagnosis, based upon the clinical tests performed (column 15, line 45).

It is noted that Armstrong et al. was previously cited and withdrawn in the Office Action of 7/16/03, in view of the amendment to step (d) in claim 1. However, in view of the amendment removing “not allowing a technician” limitation, Armstrong et al. is hereby re-instated.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Marjorie A. Moran
3/17/05

March 17, 2005
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

MARJORIE A. MORAN
PRIMARY EXAMINER